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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,771	03/11/2005	Edwin Claerebout	I-2002.015 US	5406

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PATENT DEPARTMENT
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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/527,771	CLAEREBOUT ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-49* is/are pending in the application.

4a) Of the above claim(s) *30-33,37-39,41-43 and 45-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-36,40 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

IDS filing dates 3/11/2005, 1/30/2006, and 2/10/2006.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the response filed 1/30/2006 is acknowledged. The traversal is on the following ground(s):

1. Claims 30-40, 43 and 44 possess unity of invention. Applicants assert that the protein (SEQ ID NO: 10) of Group II is encoded by the nucleic acid (SEQ ID NO: 9) of Group I, and that because the protein is novel, the claims possess unity of invention. Applicant further states that the subject matter is akin to example 39 of the International Search and preliminary examination guidelines and that according to the example, the claims possess unity of invention.

2. Applicant argues that claims 41 and 42 possess unity of invention with claims 30-40, 43 and 44 because they are dependent upon claims of Groups I or II.

3. Applicant argues that claims 45-49 possess unity of invention with claims 30-44 because they are dependent upon claims 30-44. Applicant further argues that claims 45-49 are drawn to a process of using the products of claims 30-44.

This is not found persuasive for the following reasons:

Groups I and II are drawn to nucleic acid sequences and to proteins encoded by said nucleic acid sequences, respectively. Applicant cites example 39 of the International Search and preliminary examination guidelines to buttress his argument. However, the example does not apply as applicant states. The example as cited by applicant shows an isolated protein X having SEQ ID NO: 1 and an isolated DNA molecule encoding protein X of claim 1. The instant claims are drawn to isolated nucleic acid molecules or fragments thereof and to isolated proteins or immunogenic fragments. The claims do not state that the nucleic acid molecules of Group I encode the proteins of Group II. Further, the claimed proteins include fragments that are not encoded by SEQ ID NO:1. This is akin to the alternative claim language shown in example 39, which states that in this case the claims do not share the same technical feature and therefore lack unity. Therefore, because groups I and II do not share the same technical feature, the claims do not possess unity of invention. MPEP 1.499 states that restriction is proper if the examiner finds lack of unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 30-49 are pending. Claims 30-33, 37-39, 41-43, and 45-49 are withdrawn from consideration as being drawn to non-elected inventions. Claims 34-36, 40 and 44 are currently under examination.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See, for example, p. 18. This is only exemplary and applicant should review the specification to correct any other use of embedded hyperlink and/or other form of browser-executable code.

The use of the trademark Triton X-100® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. The use of the trademark Triton X-100® is noted on p. 39. This is only exemplary and applicant should review the specification to correct any other use of trademarks.

Information Disclosure Statement

The information disclosure statements filed 3/11/2005, 1/30/2006, and 2/10/2006 have been considered. Initialed copies are enclosed.

Claim Objections

Claim 35 is objected to because of the following informalities: the claim is dependent on claim 30 that is a non-elected claim. Appropriate correction is required.

Claim Rejections

35 U.S.C. First Paragraph, Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 34-36, 40, and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 10 that corresponds to a 30 kD *Ostertagia ostertagi* protein and SEQ ID NO: 9 that corresponds to a nucleic acid sequence that encodes said 30 kD *Ostertagia ostertagi* protein. SEQ ID NO: 9 and 10 meet the written description provision of 35 USC 112, first paragraph. However, the aforementioned claims encompass sequences that have 90% homology to SEQ ID NO: 10 and to sequences that have 85% homology to SEQ ID NO: 9, fragments, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity. homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 9 and 10, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid and/or protein itself is required. See Fiers v. Revel, 25 USPQ2d

1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Therefore, only SEQ ID NO: 9 and 10, but not the full breadth of the claims, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115).

35 U.S.C. First Paragraph, Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-36, 40, and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated and purified 30 kD *Ostertagia ostertagi* protein having the sequence set forth in SEQ ID NO: 10, and for an *Ostertagia ostertagi* protein encoded by the nucleic acid sequence set forth in SEQ ID NO: 9, does not reasonably provide enablement for the myriads of other polypeptides species claimed. The specification is enabling only for claims limited to proteins represented by SEQ ID NO: 10 and for proteins encoded by the nucleic acid sequence represented by SEQ ID NO: 9 because the specification does not reasonably provide enablement for polypeptide variants having at least 90% sequence homology to SEQ ID NO: 10 (and fragments thereof) or to proteins encoded by nucleic acids having at least 85% sequence homology to SEQ ID NO: 9 (and fragments thereof). The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The claims are drawn to *Ostertagia ostertagi* proteins with 90% homology to the amino acid sequence recited in SEQ ID NO: 10 (and fragments thereof) and to *Ostertagia ostertagi* proteins encoded by a nucleic acid molecule with 85% homology to the nucleic acid sequence recited in SEQ ID NO: 9 (and fragments thereof). Said proteins have no claimed biochemical, immunological or physiological function. Protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where

such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess et al (J. of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar et al. (Molecular and Cellular Biology, 1988, 8:1247-1252) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. Clearly, proteins with up to 10% dissimilarity to the polypeptides of SEQ ID NO: 10 (or up to 15% dissimilarity to SEQ ID NO: 9) that maintained the characteristics of the polypeptides encoded by SEQ ID NO: 10 could not be predicted. Additionally, Bork (Genome Research, 2000,10:398-400) clearly teaches the pitfalls associated with comparative sequence analysis for predicting protein function because of the known error margins for high-throughput computational methods. Bork specifically teaches that computational sequence analysis is far from perfect, despite the fact that sequencing itself is highly automated and accurate (p. 398, column 1). One of the reasons for the inaccuracy is that the quality of data in public sequence databases is still insufficient. This is particularly true for data on protein function. Protein function is context dependent, and both molecular and cellular aspects have to be considered (p. 398, column 2). Conclusions from the comparison analysis are often stretched with regard to protein products (p. 398, column 3). Further, although gene annotation via sequence database searches is already a routine job, even here the error rate is considerable (p. 399, column 2). Most features predicted with an accuracy of greater than 70% are of structural nature and, at best, only indirectly imply a certain functionality (see legend for table 1, page 399). As more sequences are added and as errors accumulate and propagate it becomes more difficult to infer correct function from the many possibilities revealed by database search (p. 399, paragraph bridging columns 2 and 3). The reference finally cautions that

although the current methods seem to capture important features and explain general trends, 30% of those features are missing or predicted wrongly. This has to be kept in mind when processing the results further (p. 400, paragraph bridging cols 1 and 2). Clearly, given not only the teachings of Bowie et al., Lazar et al. and Burgess et al. but also the limitations and pitfalls of using computational sequence analysis and the unknown effects of alternative splicing, post translational modification and cellular context on protein function as taught by Bork, the claimed proteins could not be predicted based on sequence identity to SEQ ID NO: 10 or on sequence identity with the encoding nucleic acid (SEQ ID NO: 9). Further, even if a given polypeptide possesses all the structural limitations of the claimed invention, neither the specification nor any art of record teaches what that polypeptide is, what it does, does not teach a relationship to any specific disease or establish any involvement of the polypeptide in the etiology of any specific disease or teach which fragments might be active or which derivatives would function as claimed in a pharmaceutical composition. Clearly, it could not be predicted that polynucleotide, or a variant, that encodes a protein that shares only partial homology with a disclosed protein or that a protein that is encoded by a "variant" of a given SEQ ID NO: will function in a given manner. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus of proteins. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Claims 36 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to vaccine compositions comprising *Ostertagia ostertagi* proteins or fragments with 90% homology to the amino acid sequence recited in SEQ ID NO: 10 and to *Ostertagia ostertagi* proteins encoded by a nucleic acid molecule with 85% homology to the nucleic acid sequence recited in SEQ ID NO: 9.

The specification teaches that rabbits injected with a protein having the sequence set forth in SEQ ID NO: 10 produced antibodies that were able to bind to SEQ ID NO: 10. However, the

specification is devoid of any teaching that said proteins provide an effective vaccine against any disease. The rejected claims are drawn to prophylactic compositions comprising parasitic proteins against " *Ostertagia ostertagi* infection" wherein said vaccines comprise *Ostertagia ostertagi* proteins or fragments with 90% homology to the amino acid sequence recited in SEQ ID NO: 10 or *Ostertagia ostertagi* proteins encoded by a nucleic acid molecule with 85% homology to the nucleic acid sequence recited in SEQ ID NO: 9. To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The skilled artisan would clearly realize the critical deficiency of this specification with respect to vaccines. There is absolutely no demonstration of protective immunity upon administration in any animal model of disease by the proteins described in the specification. Therefore it is not clear that the described proteins are capable of generating an active immune response such as an antibody response that protects the animal against any type of disease. Although many investigators have tried to develop vaccines based on specific antigens, it is well understood that the ability of an antigen to stimulate antibody production does not necessarily correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from infection (Chandrashekar *et al.*, US Patent 6,248,329, col. 1, lines 35-41). It is well recognized in the vaccine art, that it is unclear whether an antigen derive from a pathogen will elicit protective immunity. Ellis (Chapter 29 of Vaccines, Plistkin, *et al.* (eds) WB Saunders, Philadelphia, 1998, especially p. 571, paragraph 2) exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen." The specification fails to teach that any of the proteins disclosed can produce a protective response in the host, as is requisite of a vaccine composition. In view of the lack of support in the art and specification for an effective vaccine comprising the claimed proteins, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine as claimed; therefore the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, 40 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is rendered vague and indefinite by the phrase "a vaccine for combating *Ostertagia ostertagi* infection." To combat an infection, there must be an infection to fight, however, a vaccine, by definition, prevents infection. Therefore, a composition for combating infection cannot be a vaccine.

Claim 36 is rendered vague and indefinite by the phrase "a vaccine... comprising at least one *Ostertagia ostertagi* protein or an immunogenic fragment of said protein according to claim 34." The claim can be interpreted in two ways. First, the claim can be interpreted as a vaccine comprising an immunogenic fragment of an *Ostertagia ostertagi* protein according to claim 34, or as a vaccine comprising an *Ostertagia ostertagi* protein. Second, the claim can be interpreted as a vaccine comprising an *Ostertagia ostertagi* protein according to claim 34, or as a vaccine comprising an immunogenic fragment of an *Ostertagia ostertagi* protein according to claim 34. It is unclear which of these applicant intends.

Claim 44 is rendered vague and indefinite by the phrase "a diagnostic kit comprising a suitable detection means and a protein or immunogenic fragment thereof according to claim 34." The claims can be interpreted in two ways. First, the claim can be interpreted as a kit comprising a protein and suitable detection means, or as a kit comprising an immunogenic fragment of a protein according to claim 34 and a suitable detection means. Second, the claim can be interpreted as a kit comprising a protein according to claim 34, and a suitable detection means; or as a kit comprising an immunogenic fragment of a protein according to claim 34, and a suitable detection means. It is unclear which of these applicant intends.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36 and 40 are rejected under 35 U.S.C. 102(a) as being anticipated by Claerebout et al. (Novel Approaches Meeting III, Moredun Research Institute, 7/2002, IDS filed 2/10/2006).

The instant claims are drawn to a vaccine comprising at least one *Ostertagia ostertagi* protein or an immunogenic fragment of said protein wherein the immunogenic fragment thereof has a sequence homology of at least 90% to the amino acid sequence set forth in SEQ ID NO: 10 and a pharmaceutical carrier (claim 36); and to said vaccine further comprising an adjuvant (claim 40). The claim is interpreted as a vaccine comprising at least one *Ostertagia ostertagi* protein.

Claerebout et al. disclose a vaccine comprising *Ostertagia ostertagi* protein with an adjuvant (see slides 4-5).

Claims 36 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverman (US Patent 3,395,218, 1968).

The instant claims are drawn to a vaccine comprising at least one *Ostertagia ostertagi* protein or an immunogenic fragment of said protein wherein the immunogenic fragment thereof has a sequence homology of at least 90% to the amino acid sequence set forth in SEQ ID NO: 10 and a pharmaceutical carrier (claim 36); and to said vaccine further comprising an adjuvant (claim 40). The claim is interpreted as a vaccine comprising at least one *Ostertagia ostertagi* protein.

Silverman discloses a vaccine comprising pulverized *Ostertagia ostertagi* larvae in sterile water (see column 4, lines 6-35). Whole larvae would necessarily contain at least one *Ostertagia ostertagi* protein. Silverman further discloses that said vaccine may contain suitable adjuvants (see column 3, lines 16-18).

Claim 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Pastan *et al.* (US Patent 6,232,086, May, 2001).

The instant claim is drawn to a diagnostic kit comprising a suitable detection means and a protein or immunogenic fragment wherein the immunogenic fragment thereof has a sequence homology of at least 90% to the amino acid sequence set forth in SEQ ID NO: 10. The claim is interpreted as a diagnostic kit comprising a suitable detection means and a protein.

Pastan *et al.* disclose a diagnostic kit that contains fluorescently labeled proteins (see column 22, lines 58-66).

Claims 34-36, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Coyne (US Patent 6,017,757, 1/25/2000).

The instant claims are drawn to an isolated and purified 30 kD *Ostertagia ostertagi* protein or an immunogenic fragment of said protein, wherein said protein or immunogenic fragment thereof has a sequence homology of at least 90% to the amino acid sequence as depicted in SEQ ID NO: 10 (claim 34); an *Ostertagia ostertagi* protein or an immunogenic fragment of said protein, wherein said protein or immunogenic fragment is encoded by a nucleic acid sequence that encodes an immunogenic fragment of said protein, said nucleic acid sequence or said part thereof having at least 85% homology with the nucleic acid sequence of the *Ostertagia ostertagi* protein gene as depicted in SEQ ID NO: 9 (claim 35); a vaccine for combating *Ostertagia ostertagi* infection, comprising: at least one *Ostertagia ostertagi* protein or an immunogenic fragment of said protein according to claim 34 and a pharmaceutically acceptable carrier (claim 36); and the vaccine according to claim 36, further comprising an adjuvant (claim 40).

Coyne discloses an *Ostertagia ostertagi* protein with an approximate molecular weight of 29-33 kD (see column 25, lines 14-17). Due to the similarity in molecular weight between the protein disclosed by Coyne and the protein of the instant invention it is deemed, in the absence of evidence to the contrary, that the two proteins are the same. As the amino acid sequence of a protein is an inherent property of a protein, Coyne anticipates the claimed invention since the identification of a new characteristic of a known product does not make that product patentable (see MPEP 2112 R-3). The term "vaccine" is an intended use and is given no patentable weight,

therefore the claims are drawn to a composition comprising an isolated and purified 30 kD *Ostertagia ostertagi* protein or an immunogenic fragment of said protein, wherein said protein or immunogenic fragment thereof has a sequence homology of at least 90% to the amino acid sequence as depicted in SEQ ID NO: 10; an *Ostertagia ostertagi* protein or an immunogenic fragment of said protein, wherein said protein or immunogenic fragment is encoded by a nucleic acid sequence that encodes an immunogenic fragment of said protein, said nucleic acid sequence or said part thereof having at least 85% homology with the nucleic acid sequence of the *Ostertagia ostertagi* protein gene as depicted in SEQ ID NO: 9. Moreover, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gangle whose telephone number is 571-272-1181. The examiner can normally be reached on M-F 8:00 am - 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Brian Gangle
AU 1645

ROBERT ZEMAN
PATENT EXAMINER